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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,851	11/14/2005	Kunihiko Matsushita	KPO-TSC-P2/TK-91/US	2134
44702 7590 02/02/2010 OSTRAGER CHONG FLAHERTY & BROITMAN PC 570 LEXINGTON AVENUE FLOOR 17 NEW YORK, NY 10022-6894				
EXAMINER				
MERCIER, MELISSA S				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
02/02/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/556,851

**Applicant(s)**

MATSUSHITA ET AL.

**Examiner**

MELISSA S. MERCIER

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/200)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicants Remarks and Amended Claims filed on November 10, 2009 is acknowledged. Claims 1-12 are pending in this application.

### ***Withdrawn Rejections***

#### ***Claim Rejections - 35 USC § 103***

The rejection of claims 1-3, 5-7, and 9-11 under 35 U.S.C. 103(a) as being unpatentable over Hirano et al. (JP 11-001441) of record, in view of Blank et al. (US Patent 5,128,138) has been withdrawn in view of Applicants arguments regarding the PVP polymer.

The rejection of claims 4, 8, and 12 under 35 U.S.C. 103(a) as being unpatentable over Hirano et al. (JP 11-001441) of record, in view of Blank et al. (US Patent 5,128,138) and further in view of Azuma et al. (US Patent 5,200,190) has been withdrawn in view of Applicants arguments regarding the PVP polymer.

### ***Newly Applied Rejections/Objections***

#### ***Claim Objections***

Claim 5 is identified as "currently amended" however; the Examiner is unable to determine what has been amended in the claim. It appears to be a typographical error. The components are also all identified as a. It is suggested Applicant amend the claim to recite components a-d.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5-7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirano et al., hereinafter referred to as Hirano (JP 11-001441) of record, in view of Grawe et al., hereinafter referred to as Grawe (US Patent 6,902,741).

Hirano discloses a percutaneous absorption patch comprising:

- a. 10-30% of a styrene-isoprene-styrene block copolymer;
- b. 10-60% of a softening agent;
- c. 20-60% of a tackifying resin; and

d. 1-10% of hexylene glycol, all based on % weight. The medicinal ingredient is an estrogen, such as estradiol or progesterin such as norethisterone at a level of 0.1-10% weight (abstract). Rosin esters are disclosed for use as the tackifiers (paragraph 0016).

The patch is a laminated film (paragraph 0017).

Additives such as antioxidants, additional adhesives, water absorbing polymers, bulking agents, moisturizers and absorption enhancers can be added (paragraph 0019).

The use of polyvinylpyrrolidone is not disclosed. 17- $\beta$ -estradiol is also not disclosed.

Grawe discloses transdermal systems including a sex hormone containing adhesive matrix, which contains inclusions of a sex hormone in a hydrophilic non-cross

linked polymer in dissolved or dispersed form. The hydrophilic non cross linked polymer can be polyvinylpyrrolidone (PVP) (abstract).

The sex hormone can be 17-beta-estradiol (column 4, line 20) among other estradiols, thereby showing them to be functional equivalents.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added used the 17-beta-estradiol taught by Grawe in the formulation of Hirano since they are disclosed to be functional equivalents. Grawe additionally discloses the use of the hydrophilic non cross linked polymer allows for high active substance loading and good storage stability.

Claims 4, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirano et al., hereinafter referred to as Hirano (JP 11-001441) of record, in view of Grawe et al., hereinafter referred to as Grawe (US Patent 6,902,741) and further in view of Azuma et al., hereinafter referred to as Azuma (US Patent 5,200,190).

The combined teachings of Hirano and Grawe are discussed above and applied in the same manner.

Hirano and Grawe do not disclose the components of the laminated patch.

Azuma discloses percutaneous pharmaceutical preparations for the administration of estradiols (abstract). Laminated patches comprising backing layers of polyethylene terephthalate, and cellulose acetate, ethyl cellulose, vinyl acetate-vinyl chloride copolymers, nylon, ethylene-vinyl acetate copolymers, plasticized polyvinyl

chloride, polyurethane, polyethylene, polyvinylidene chloride and aluminum, which Applicant has identified as suitable flexible polymer films in the specification on page 10.

The thickness of the layers were not disclosed, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have prepared a film in varying thicknesses based on the needs of the patch. Applicants attention is directed to MPEP 2144.04 IV, which discloses changes in size and shape are not patentably distinct over a device which would perform the same function, in this cases both Azuma and Hirano are drawn to external patches for percutaneous delivery of estradiol.

### ***Conclusion***

Due to the new grounds of rejection presented in this office action, this action is made Non-Final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner, Art Unit 1615